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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,069	07/24/2003	Garret D. Cawthon	37013-6	9758

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EXAMINER

LAMM, MARINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/626,069

Applicant(s)

CAWTHON, GARRET D.

Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-73 is/are pending in the application.
- 4a) Of the above claim(s) 61-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Acknowledgment is made of the amendment filed 3/28/05. Claims pending are 39-73. Claims 39 and 50 have been amended. Claims 61-73 have been withdrawn from consideration as directed to the invention non-elected without traverse.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 51 recites the limitation "comfrey" in line 3. There is insufficient antecedent basis for this limitation in the claim because Claim 39 was amended to delete "comfrey".

#### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of Claims 39, 40, 44-48 and 54-58 under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245) is maintained for the reasons of the record.
5. The rejection of Claims 39, 40, 44 and 54-58 under 35 U.S.C. 103(a) as being unpatentable over Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254) is maintained for the reasons of the record.
6. The rejection of Claims 41-43, 59 and 60 under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245) and

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further in view of Boussouira et al. (US 6,103,247) is maintained for the reasons of the record.

7. The rejection of Claims 39, 49 and 50 under 35 U.S.C. 103(a) as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Mulder (US 5,536,502) and Moss (US 4,816,254) is maintained for the reasons of the record.

8. The rejection of Claims 51 and 52 under 35 U.S.C. 103(a) as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Huffstutler (WO 92/06701) is maintained for the reasons of the record.

9. The rejection of Claim 53 under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Huffstutler (WO 92/06701) as applied to Claim 51 above and further in view of Moss (US 4,816,254) is maintained for the reasons of the record.

### ***Response to Arguments***

10. Applicant's arguments filed 3/28/05 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the Adams et al. and Clark et al. references (see pp. 13-18 of the reply), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves

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or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teachings of Adams et al. pertaining to the difficulties in "protecting the baby's bottom from prolonged exposure to the effects of ammonium compounds on the baby's skin" and caring for skin irritations such as chapping, rashes, reddening, tenderness and the like, and the teachings of Clark et al. indicating success in using micronized zinc oxide, silicone and/or petrolatum in topical barrier compositions, in the face of having to solve a similar problem would have led one of ordinary skill in the art at the time the invention was made to combine the references to solve a well known problem in the art. The strongest rationale for combining references is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. See *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983) and MPEP 2144.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (see p. 19 of the reply), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's

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disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Further, the Applicant argues that the references "actually teach away from one another" because "the notion of a viscous paste, ointment or cream [in Clark et al.] is directly at odds with the notion of a sprayable composition [in Adams et al.]." See p. 19 of the reply. In response, it is well established that a prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). In this case, both references are concerned with solving the same problem, i.e. protecting the skin from irritation and treating diaper rash, as discussed above. Clark et al. suggest using zinc oxide, silicone oils and/or petrolatum for this purpose. Adams et al. teaches that diaper rash treating compositions can be formulated as aerosols, among other forms. There is nothing in Adams et al. that "would discourage" a person of ordinary skill from using ingredients of Clark et al. and formulating them into an aerosol composition. There is no suggestion or evidence in either reference that adding zinc oxide or silicone or even petrolatum of Clark et al. would render the compositions and method of Adams et al. inoperable, especially in view of the Clark's teaching of concentrations as low as 1% by weight. This is further supported by the teachings of Mulder, who teaches using zinc

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oxide as well as lanolin oil, waxes, fatty acids, fatty esters and other high viscosity ingredients in spray-on wound healing formulations. See col. 5, Example 1 of Mulder.

In response to applicant's argument that there is no suggestion to combine the Gebhart et al. and Moss references (see p. 20 of the reply), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gebhart et al. teach aerosol compositions for the treatment of skin irritations such as diaper rash containing, among other ingredients, vitamins A and D. Moss teaches protective compositions for the treatment of skin irritations such as diaper rash, containing zinc oxide, which has antiseptic activity, and cod liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to at least use cod liver oil of Moss instead of vitamins A and D of Gebhart et al. for the same purpose and with a reasonable expectation of achieving the same results as set forth in the Gebhart et al. reference. Alternatively, one having ordinary skill in the art would have been motivated to use cod liver oil of Moss instead of vitamins A and D of Gebhart et al. because cod liver oil contains vitamins A and D **and** promotes rapid, scar-free healing as suggested by Moss,

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i.e. it provides additional beneficial effects. As discussed above, the strongest rationale for combining references is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. See *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983) and MPEP 2144.

Lastly, the Applicant argues that "the Mulder reference does not even relate to a diaper rash treatment compositions." See p. 21 of the reply. In response, Mulder relates to non-irritating wound healing compositions, which is from the same field of endeavor as the Applicant's invention because both inventions are concerned with skin healing.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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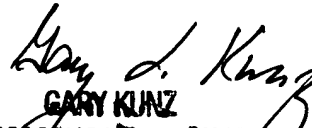
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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6/11/05

